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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,807	01/17/2001	Maria Palasis	12013/58101	4398

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NEW YORK, NY 10004

EXAMINER

THANH, LOAN H

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,807

Applicant(s)

PALASIS, MARIA

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-15 and 17-27 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6, 7, 11, 13, 15, 17-19, 22 and 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 8-10, 12, 14, 20, 21 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Response to the drawing objection is being maintained. In view of the declaration under 35 CFR 1.132 filed 05/24/05, the drawing objections have not been overcome. Applicant has shown no evidence to show that the proposed drawing as configured was disclosed as originally filed. The balloon as described in the specification does not specifically show the drawing as now proposed. The specificity of the proposed drawing is beyond the general description of the application as originally filed.

Drawings

The proposed drawing correction and/or proposed substitute sheets of drawings filed 11/15/04 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.121(f) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support the specifics of the showing of the grooves as characterized in the amended figure 5.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second balloon positioned between the dilation bladder and the first balloon and the grooves in the first balloon must be shown or the feature(s) *canceled from the claim(s)*. **No new matter should be entered.**

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

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replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 8, 12,14,20,21, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty (USPN 4,338,942) in view of Nicholas et al. (USPN 5,588,962).

Fogarty discloses the invention as substantially claimed. Fogarty discloses a dilatation catheter assembly comprising a catheter, a source of fluid in communication with the first internal lumen, a first balloon 48 having an exterior and interior surface, the first balloon having a measurable elasticity and made of latex and a dilation balloon 34 having a second internal lumen the dilation bladder having a measurable elasticity and made of vinyl plastic, the elasticity of the inflatable balloon 48 being greater than the elasticity of the dilation bladder 34. See col. 2 lines 16-32. See figures 1-4. Fogarty teaches a the balloon to remove build up of deposits on the blood vessel such as arteriosclerotic plaque or atheroma which occlude blood vessels. However, Fogarty does not teach the first inflatable balloon to have an exterior surface partially covered with a therapeutic agent. Nicholas et al. disclose a system for removing and preventing deposits which occlude the blood vessel comprising a balloon catheter assembly for angioplasty or dilatation to prevent restenosis having a balloon 8 including a coating 16 having a drug 14 for localized treatment of the target site. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the exterior surface of the balloon of Fogarty with the drug coated balloon surface as taught by Nicholas et al. in order to provide localized drug delivery.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty (USPN 4,338,942) in view of Nicholas et al. (USPN 5,588,962).

Fogarty in view of Nicholas et al. disclose the claimed invention (See above) except for the material of the balloon being silicone or polyurethane. Fogarty in view of Nicholas et al. teach the material of the first balloon to be elastic such as latex. It would

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have been obvious to one of ordinary skill in the art at the time the invention was made to modify the materials of the first balloon such as any other elastic material that is well known and medically used in the medical arts to suit the area to which it would be applied to , since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended uses as a matter of obvious engineering choice lacking any criticality. In re Leshin , 125 USPQ 416.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty (USPN 4,338,942) in view of Nicholas et al. (USPN 5,588,962) and further in view of Lampropoulos et al. (SUSPN 5,472,424) .

Fogarty in view of Nicholas et al. disclose the claimed invention (See above) except for the step of measuring the volume of fluid forced into the expandable membrane/ balloon. Lampropoulos et al. disclose a balloon catheter used in the medical setting for monitoring, displaying, recording and controlling the inflation of the balloon. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to modify the balloon catheter system of Fogarty in view of Nicholas et al. as taught by Lampropoulos et al. in order to prevent over inflation of the balloon catheter which would be detrimental to the patient's health.

Response to Arguments


Applicant's arguments with respect to claims 1-4,6-15,17-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


LoAn H. Thanh
Primary Examiner
Art Unit 3763

LT